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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/916,235

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Theodore C. Johnson

13724-850 (37167)

6858

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09/11/2002

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EXAMINER

VRETTAKOS, PETER J

ART UNIT

PAPER NUMBER

3739

DATE MAILED: 09/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/916,235

Applicant(s)

JOHNSON ET AL.

Examiner

Peter J Vrettakos

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 64 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is unclear as "one of a resistance gradient or a resistance gradient" are the same things.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6, 7, 10-13, 15-18, and 21-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Gough et al. ('847).

Independent claim 1

Gough et al. (Gough) discloses an apparatus and method for detecting and treating a tumor using tissue localized volumetric impedance measurements comprising an elongated impedance measurement apparatus (10) including an impedance sensor array (24; column 6 lines 42-43) having a plurality of resilient members (18) deployable with curvature (see figure 3) and configured to sample tissue impedance through a

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plurality of conductive pathways (sensors in a configuration which lie substantially along resilient members as disclosed in column 5 lines 64-65), as well as an energy delivery device (12), a power supply (20), and a switching device / logic resources / processor (38,50).

Further, Gough discloses positioning or introducing the apparatus at a specific site within a sample volume as illustrated in figure 3, deploying the impedance array to make impedance measurements through a plurality of conductive pathways (implicit), and determining tissue condition of the sample volume utilizing information from the impedance measurements in column 4 lines 63-67 and column 6 lines 28-34. Gough goes on to propound that energy is delivered from the energy delivery device to ablate the tumor in column 7 lines 5-7.

Dependent claims

Re: claim 2, Gough designates each of the sensors as element 24 indicating non-selective application (application of one means application of all sensor members). From this, one can surmise that the impedance measurements taken from the sensors are done so simultaneously. Selective activation (non-simultaneous) would most likely be accompanied by at least a designation system shown in the figures in which the sensors were denoted as 24a, 24b, etc.

Re: claim 3, Gough discloses the treatment of tumors, *inter alia*, in column 4 lines 63-67.

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Re: claim 4, Gough discloses a plurality of conductive pathways. It is inherent that the individual impedance measurements determined along each pathway would be integrated or combined to provide a single impedance value to the controller.

Re: claims 6, 7, 10, 11, 15, Gough discloses the ability to monitor tumor volume (iv), developing ablation volume (i), and temporal titration of the amount of ablative treatment (iii) in column 6 lines 28-33.

Re: claims 12 and 13, Gough illustrates that the plurality of conductive pathways are evenly distributed within the sample volume in figure 3. Note, this statement is made assuming that the sensors (24) are not merely placed on the tip of the resilient members (18), but substantially along the length of the resilient members as disclosed in column 5 lines 64-65 and mentioned in this office action above. (In this configuration, the longitudinal sensors 24 make up the "conductive pathways").

Re: claims 16, 17, 18, 24, 25, Gough implicitly discloses sampling impedance at more than one time and making a treatment endpoint decision responsive to a comparison of the sampled impedances. This is done in column 6 lines 31-32, which reads, "whether or not further ablation is needed" implying that temporal measurements are taken during application that dictate future ongoing treatment. Moreover, ablative therapy parameters are adjusted in response to comparisons of ongoing impedance measurements as implied in column 6 lines 26-30, which reads, "Sensors permit accurate measurement of (impedance) at a tissue site in order to determine... the amount of ablation."

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Re: claims 21 and 22, Gough inherently discloses first and second (plurality) conductive pathways from common origins (40; figure 9). Further, Gough discloses primary (14) and secondary (16) antennas (to which the sensors lie upon).

Re: claim 23, Gough discloses selective placement of the antennas, thereby effecting the resulting angles between them allowing for sample volume definition. Note column 8 lines 61-64.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5,8, 9, 14, 19, 20, 26-44, 48-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gough in view of Pearlman ('742).

Gough, which has been described above, neglects to disclose *complex* impedance measurements, *inter alia*.

Re: claim 40, Gough discloses a display (36) for signaling tissue and ablation conditions. Note column 10 lines 2-4.

Re: claims 5,20,26,27,29, and 60, Pearlman discloses a method of tissue type characterization (see abstract) based on complex impedance measurements utilizing a

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reference impedance measurement for greater accuracy as disclosed in column 19 line 59 through column 20 line 5.

Re: claims 41 and 59, Pearlman also discloses determining real and imaginary components of the complex impedance measurements. Note column 4 lines 38-44.

Re: claims 8,32, and 48, Pearlman alleges that measurements including capacitance can be made at single discrete frequencies in column 22 lines 7-17, and further asserts sweeping samples of impedance measurements in column 22 line 16-17.

Re: claims 43 and 44, Pearlman discloses calculating the phase angle of impedance measurements in column 21 lines 5-15 especially lines 13-14.

Re: claim 56, Pearlman discloses the use of a (Fourier) transform function in column 21 lines 30-33.

Therefore, it would have been obvious to one of ordinary skill in the art to modify Gough in view of Pearlman by including as a method step the measurement or calculation of complex impedance including capacitance, real and imaginary parts of the complex impedance, phase angle, and a reference impedance in order to provide more complete insight into the dielectric properties of the targeted tissue.

Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gough in view of Pearlman and further in view of Pacela ('359).

Gough and Pearlman, which have been described above, neglects to disclose the use of impedance vectors.

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Pacula discloses an impedance measurement system in which the use of impedance vectors is put forth in column 7 lines 55-59.

Therefore, it would have been obvious to one of ordinary skill in the art to modify Gough in view of Pearlman and further in view of Pacela by including as a method step the measurement of complex impedance vectors in order to provide more complete insight into the dielectric properties of the targeted tissue.

Claims 46 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gough in view of Pearlman and further in view of Kun et al. (272).

Gough and Pearlman, which have been described above, neglects to disclose the use of locus values.

Kun et al. discloses a tissue impedance measurement system that determines the locus of an impedance measurement "to find the tissue's physiological characteristics" at different times. Note column 5 lines 59-62.

Therefore, it would have been obvious to one of ordinary skill in the art to modify Gough in view of Pearlman and further in view of Kun et al. by including as a method step the determining of impedance loci in order to provide more complete insight into the dielectric properties of the targeted tissue.

Conclusion

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The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Chance ('460), King et al. ('730), Adachi et al. ('726), Inokuchi et al. ('258), Fenn ('737), Kasevich ('452).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J Vrettakos whose telephone number is 703 605 0215. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C Dvorak can be reached on 703 308 0994. The fax phone numbers for the organization where this application or proceeding is assigned are 703 746 7013 for regular communications and 703 746 7013 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 0858.



Pete Vrettakos
September 3, 2002

PV

LINDA C. M. DVORAK
SUPERVISORY PATENT EXAMINER
GROUP 3700